

EXHIBIT 5

GAO

Report to Congressional Committees

September 2001

MEDICARE

Payments for Covered Outpatient Drugs Exceed Providers' Cost



G A O

Accountability * Integrity * Reliability

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Abbreviation

AMP	Average Manufacturer Price
AWP	Average Wholesale Price
BBRA	Balanced Budget Refinements Act of 1999
BESS	Part B Extract and Summary System
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CMS	Centers for Medicare and Medicaid Services
DME	Durable Medical Equipment
DOD	Department of Defense
DOJ	Department of Justice
ESRD	End-Stage Renal Disease
FSS	Federal Supply Schedule
GPO	Group Purchasing Organization
HCFA	Health Care Financing Administration
HCPCS	HCFA Common Procedure Coding System
HHS	Health and Human Services
NDC	National Drug Code
OBRA	Omnibus Budget Reconciliation Act
OIG	Office of the Inspector General
PBM	Pharmacy Benefits Manager
PHS	Public Health Service
VA	Department of Veterans' Affairs
WAC	Wholesale Acquisition Cost



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While Medicare does not have a comprehensive outpatient drug benefit, certain drugs and biologicals¹ are covered under part B of the program.² In general, drugs are covered if they cannot be self-administered and are related to a physician's services, such as cancer chemotherapy, or are provided in conjunction with covered durable medical equipment (DME), such as inhalation drugs used with a nebulizer.³ In addition, Medicare covers selected immunizations and certain drugs that can be self-administered, such as blood clotting factors and some oral drugs used in association with cancer treatment and immunosuppressive therapy. Medicare spending for these drugs totaled almost \$4 billion in 1999.⁴

Recent reports by the Department of Health and Human Services' (HHS) Office of Inspector General (OIG), the Department of Justice (DOJ), and the House Committee on Commerce found that in some cases Medicare's payments for part B-covered drugs were significantly higher than physicians' and other providers' actual costs of acquiring these products. They found that the average wholesale prices (AWP)—the "list prices" or "sticker prices" set by drug manufacturers and used by Medicare to calculate payment rates—were not representative of the actual costs of these drugs to providers. The Health Care Financing Administration (HCFA)⁵ initiated steps to reduce Medicare payment for some drugs. The agency issued a program memorandum in September 2000 that authorized

¹For the remainder of this report, we will refer to part B-covered drugs and biological products, such as clotting factors used to treat hemophilia, as "drugs."

²Medicare part B or Supplementary Medical Insurance provides coverage for certain physician, outpatient hospital, laboratory, and other services to beneficiaries who pay monthly premiums.

³A nebulizer is a device driven by a compressed air machine. It allows the patient to take medicine in the form of a mist (wet aerosol). It consists of a cup, a mouthpiece attached to a T-shaped part or a mask, and thin, plastic tubing to connect to the compressed air machine.

⁴The Medicare program payment is 80 percent of the total payment, or \$3.2 billion; beneficiaries are responsible for the remaining 20 percent.

⁵HCFA was renamed the Centers for Medicare and Medicaid Services in June 2001; we continue to refer to the agency as HCFA when discussing actions it took under that name.

the use of prices obtained in DOJ's investigations of providers' drug acquisition costs to set Medicare payment rates for a subset of covered drugs, which would have lowered Medicare payment for these products. However, HCFA retracted the original program memorandum in November 2000.

While physicians—particularly oncologists—and other health care providers such as pharmacy suppliers acknowledge that they can purchase drugs for prices lower than Medicare payments, they contend that they need drug payments in excess of their actual costs to compensate for inadequate or nonexistent Medicare payments for administering the drugs. Specifically, oncologists argue that Medicare's physician payment system does not adequately reimburse them for their costs of administering chemotherapy. Further, they suggest that some providers, particularly those who purchase drugs in low volume, may not have access to low drug prices, because the lowest prices reflect volume discounts and other factors. They assert that beneficiary access could be impaired if Medicare drug payments are reduced.

In a forthcoming report mandated by the Balanced Budget Refinements Act of 1999 (BBRA),⁶ we examine the adequacy of Medicare's physician payments to oncologists.⁷ We conclude that the basic methodology HCFA used to establish the fees is sound. We found that payments to oncologists are 8 percent higher than they would have been if the prior charge-based method had been maintained. We also determined that oncologists' payments relative to their estimated practice expenses are close to the average for all specialties. However, we identify modifications to the basic method that substantially lowered payments for certain services, including most chemotherapy administration. In our report, we make recommendations to improve Medicare's physician payment system.

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA),⁸ required that we determine whether Medicare is reimbursing physicians and other providers adequately for covered drugs and related services. It also stipulated that the Medicare program make no

⁶P.L. 106-113, Appendix F, Sec. 213(a), 113 Stat. 1150, 1501A-350.

⁷See our forthcoming report *Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements* (GAO-02-53, October 2001).

⁸P.L. 106-554, Appendix F, Sec. 429, 114 Stat. 2763, 2763A-522.

reductions to drug payments until we complete our work. As agreed with the committees of jurisdiction, our analysis addressed the following questions: (1) What are physicians' costs of providing drugs relative to applicable Medicare payments? (2) What are other providers' costs of providing drugs relative to applicable Medicare payments? (3) What are the methods that public and private payers use to establish payments for providing these drugs? This legislation also directed that we take into account the results of the study of oncology physician payments mandated by BBRA in evaluating drug acquisition costs relative to their Medicare payments.

To answer these questions, we interviewed officials at the Centers for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), HHS OIG, and DOJ. We also interviewed and solicited information about drug acquisition costs and costs related to drug administration from professional associations representing physicians and nonphysician providers, such as DME or pharmacy suppliers. We used pricing data from pharmaceutical wholesalers, group purchasing organizations (GPO), specialty pharmacies, DME pharmacy suppliers, and physicians, including several physicians we identified as billing for low volumes of Medicare-covered drugs. We attempted to obtain pricing information directly from additional major wholesalers and group purchasing organizations, but these entities did not provide the information we requested by the time we finalized this report. We interviewed representatives from large managed care organizations regarding the methods they used to purchase or pay for pharmaceuticals, as well as the purchase prices they were able to obtain. We also interviewed staff members at the companies that publish the major price reporting compendia on average wholesale prices for drugs.

We conducted quantitative analyses using data from HCFA and other sources. We used 1999 drug claims data from HCFA to determine which covered drugs accounted for the most spending and volume. For detailed analysis, we selected the 20 drugs with the highest total Medicare expenditures and the 20 drugs with the highest volume; the results of our analysis indicated that 35 different drugs accounted for 82 percent of total Medicare drug spending and 95 percent of total drug units.⁹ We obtained prices for 31 of the 35 individual drugs. We did our work in accordance with generally accepted government auditing standards from January

⁹Volume for a drug is measured in terms of the number of Medicare-allowed services.

through August 2001. A detailed discussion of our scope and methodology is in appendix I.

Results in Brief

Physicians are able to obtain Medicare-covered drugs at prices significantly below current Medicare payments, which are set at 95 percent of AWP. Wholesalers' and GPOs' prices that would be generally available to physicians were considerably less than AWP used to establish the Medicare payment for these drugs. The difference between these prices and AWP for physician-administered drugs in our sample varied by drug. For most physician-administered drugs, the average discount from AWP ranged from 13 percent to 34 percent; two physician-administered drugs had discounts of 65 percent and 86 percent. Our survey of physicians who billed Medicare for low volumes of drugs used in cancer treatment indicated they received discounts that were as large as or larger than widely available discounts for 11 of the 16 products for which they were able to provide price information. Physicians are reimbursed under the physician fee schedule for the costs of administering chemotherapy drugs, which account for most of Medicare's drug spending. HCFA deviated from the basic methodology for determining practice expense payments for certain services, including chemotherapy administration by nonphysicians, which reduced Medicare's practice expense payment for most chemotherapy administration services. However, even with this alternative methodology, oncologists' average practice expense payments in 2001 are 8 percent higher than what they would have been had charge-based payments continued.

Other suppliers are also able to purchase drugs at prices that are considerably less than the AWP used to establish the applicable Medicare payment. Pharmacy suppliers were the predominant billers for 10 of the high-expenditure and high-volume Medicare-covered drugs we analyzed. In general, these suppliers provide two types of drugs—drugs administered through DME and covered oral drugs, such as certain immunosuppressives. Widely available prices in 2001 reflected average discounts of 78 percent from the AWP for ipratropium bromide and 85 percent for albuterol, two DME-delivered inhalation therapy drugs that account for most of Medicare payments to pharmacy suppliers. Medicare pays a monthly fee to pharmacy suppliers for dispensing these and certain other respiratory therapy drugs. Also, suppliers generally receive a payment from Medicare for DME and supplies. Although there has been no recent analysis of the adequacy of Medicare's DME payments, there are indications that the payments may be above current market rates. Wholesaler and GPO prices for two of the high-volume oral drugs averaged

14 percent and 77 percent below AWP. Medicare makes no separate payments for costs associated with supplying or administering oral drugs.

Private and other public payers use differing payment methods for drugs and their administration. Private health plans use their drug-purchase and patient volume to negotiate favorable prices for drugs and the physician and supplier services related to supplying or delivering the drugs. Other public payers also use their purchasing volume along with information about actual transaction prices from private payers to lower their drug payments. VA and certain other government agencies use the Federal Supply Schedule (FSS) prices for drugs.¹⁰ State Medicaid programs reimburse for drugs using formulas based on standard price lists but subsequently receive rebates from the manufacturers calculated using the average manufacturer price (AMP), to substantially lower their net prices for drugs.¹¹ Both the FSS and the AMP are derived from actual market transaction data reported by drug manufacturers. In limited instances, VA also uses competitive bidding approaches to obtain lower drug prices, an approach that Medicare has used in limited demonstration projects.

We recommend that the Administrator of CMS take steps to begin reimbursing providers for part B-covered drugs and related services at levels reflecting providers' acquisition costs using information about actual market transaction prices. We recommend that the CMS Administrator evaluate expanding competitive bidding approaches to setting payment levels. We also recommend that the CMS Administrator closely monitor beneficiary access to covered drugs in light of any changes to reimbursement.

¹⁰FSS prices are available to any federal agency that directly procures pharmaceuticals, including VA medical centers, the Department of Defense (DOD), the Bureau of Prisons, the Public Health Service (PHS), and other designated entities such as the District of Columbia, U.S. territorial governments, the Indian Health Service, and some state veterans homes. Manufacturers must also sell brand-name drugs listed on the FSS to four federal drug purchasers—VA, DOD, PHS, and the Coast Guard—at a price at least 24 percent lower than the nonfederal average manufacturer price, a ceiling price that is lower than the FSS price for many drugs.

¹¹State Medicaid programs generally pay pharmacies a dispensing fee for each prescription and physicians a fee for administering the drugs.

Background

Although Medicare reimburses providers for roughly 450 unique drugs under part B, a small number of products accounted for the majority of Medicare spending and volume.¹² In 1999, the 20 highest expenditure drugs accounted for 75 percent of total Medicare drug spending and the 20 highest volume drugs accounted for 93 percent of total units.¹³ (See tables 1 and 2.) Combined, these two groups of drugs yielded 35 unique drugs, accounting for 82 percent of total drug spending and 95 percent of total drug units.¹⁴

¹²Each covered drug is identified by an alphanumeric code under the HCFA Common Procedure Coding System (HCPCS), which specifies the drug name, method of administration, and dosage.

¹³Our analysis of drug acquisition costs excluded four high-volume and high-expenditure drugs. Specifically, we excluded a code for “not otherwise classified antineoplastic drugs,” two antihemophilia clotting factors, and a radiopharmaceutical. We could not collect acquisition cost data on “not otherwise classified antineoplastic drugs” because it does not refer to a specific product. The clotting factors, which are typically billed by non-physician suppliers, were not included for two reasons. First, we were unable to obtain adequate pricing information for these products, a problem also encountered by HHS OIG in its prior work on drug reimbursement. Second, these products differ significantly from other pharmaceutical products discussed in this report. Their source material is collected from human donors; their manufacturing, storage, and distribution processes differ from other products; and they are administered to a very small patient population. The excluded radiopharmaceutical, Technetium TC Sestamibi, is used by cardiologists in certain diagnostic imaging procedures. Since Medicare only began requiring data on AWP to reimburse for radiopharmaceutical products in 2001, these data are currently being developed.

¹⁴Units are defined as the number of claims for each drug times the number of units specified by its HCPCS label.

Table 1: Medicare Part B Drugs by Share of Total Medicare Drug Spending, 1999

Drug name	Share of total Medicare drug spending (percentage)
Leuprolide acetate (for depot suspension)	15.1
Epoetin alpha for non-ESRD use	9.5
Goserelin acetate implant	7.9
Ipratropium bromide, unit dose form	6.4
Albuterol, unit dose form	6.3
Paclitaxel	6.2
Carboplatin	2.9
Pamidronate disodium	2.8
Irinotecan	2.0
Gemcitabine HCl	1.9
Rituximab	1.8
Filgrastim (G-CSF) 480 mcg	1.7
Leucovorin calcium	1.6
Docetaxel	1.5
Factor VIII (antihemophilic factor, recombinant)	1.3
Technetium TC Sestamibi	1.2
Hylan G-F 20	1.2
Filgrastim (G-CSF) 300 mcg	1.2
Not otherwise classified antineoplastic drugs	1.2
Dolasetron mesylate, injection	1.2
Subtotal, 20 highest-expenditure drugs and biologicals	74.9
All other Medicare-covered drugs and biologicals	25.1
Total	100.0

Source: GAO analysis of data from the Medicare Part B Extract and Summary System (BESS).

Table 2: Medicare Part B Drugs by Share of Total Medicare Units, 1999

Drug name	Share of total units (percentage)
Albuterol, unit dose form	65.8
Ipratropium bromide, unit dose form	8.2
Epoetin alpha for non-ESRD use	3.4
Dolasetron mesylate, injection	3.3
Albuterol, concentrated form	2.6
Mycophenolate mofetil, oral	1.7
Cromolyn sodium, unit dose form	1.2
Heparin sodium	1.0
Cyclosporine, oral	0.9
Ondansetron HCl, injection	0.8
Tacrolimus, oral	0.7
Prednisone, oral	0.6
Acetylcysteine, unit dose form	0.5
Botulinum toxin, type A	0.5
Imiglucerase	0.4
Factor VIII (antihemophilic factor, human)	0.4
Dexamethasone sodium phosphate	0.4
Leucovorin calcium	0.3
Saline solution, sterile	0.3
Granisetron HCl, injection	0.3
Subtotal, 20 highest-volume drugs and biologicals	93.3
All other Medicare-covered drugs and biologicals	6.7
Total	100.0

Note: Units are defined as the number of Medicare-allowed services. Each drug has a standard unit dosage specified by the HCPCS code.

Source: GAO analysis of data from BESS.

The drugs provided by physicians account for the largest share of Medicare expenditures for drugs under part B, while billing volume is dominated by the drugs provided by pharmacy suppliers. Drugs provided in the physician office setting accounted for over 75 percent of Medicare spending for drugs in 1999. (See table 3.) Three specialties, hematology/oncology, medical oncology, and urology, bill Medicare primarily for drugs used in the treatment of cancer and represented 80 percent of total Medicare payments to physicians for drugs. By contrast, pharmacy suppliers accounted for over 80 percent of Medicare drug billing volume and less than 20 percent of corresponding payments. Two inhalation therapy drugs dominated these home-administered products, accounting for 88 percent of Medicare volume in the home setting. When the drug is delivered in a physician's office, Medicare makes a separate

additional payment through the physician fee schedule for the physician or his or her staff administering a drug. When the drug is administered via DME in the home, Medicare pays separately for DME, the drug, and associated supplies as well as a monthly dispensing fee for providing nebulizer drugs.

Table 3: Medicare Part B Drug Spending and Volume by Place of Service, 1999

Place of service	Total spending	Share of total spending (percentage)	Total units	Share of total units (percentage)
Physician office	\$3,021,662,605	76.2	142,247,564	14.9
Home	727,559,447	18.3	759,461,862	79.7
Other ^a	218,297,305	5.5	51,770,956	5.4
Total	\$3,967,519,357	100.0	953,480,382	100.0

^aOther includes, for example, immunization centers, end-stage renal disease treatment facilities, and independent laboratories.

Note: Medicare's payment is 80 percent of the allowed amount and the beneficiaries' share is 20 percent, after they have fulfilled their annual deductible requirements. Units are defined as the number of Medicare-allowed services, as specified by the HCPCS code.

Source: GAO analysis of data from BESS.

Medicare Payments for Drugs Are Based on Published AWP

Medicare bases its reimbursement to physicians and other providers of drugs on AWP, which is often described as a "list price," "sticker price," or "suggested retail price," reflecting the fact that AWP is not necessarily the price paid by a purchaser or a consistently low or "wholesale" price. AWP is published for each drug identified by a National Drug Code (NDC).¹⁵ Manufacturers periodically report AWP for NDCs to publishers of drug pricing data, such as the Medical Economics Company, Inc., which publishes the Red Book, or First Data Bank, which compiles the National Drug Data File. Publishers of AWP and other drug prices stated that they list the prices as reported to them by the manufacturers. There is no required frequency for manufacturers to report AWP, but publishers said they attempt to update AWP at least annually. Medicare carriers, the contractors responsible for paying part B claims, use published AWP to

¹⁵NDCs are the universal product identifiers for drugs for human use; the Food and Drug Administration assigns the first part of the NDC, which identifies the firm that manufactures, repackages, or distributes a drug. Each NDC is specific to a chemical entity, dosage form, manufacturer, strength, and package size. For example, a drug made by one manufacturer, in one form and strength, but in three package sizes, would have three NDCs.

determine the Medicare-allowed amount, or payment level, which is 95 percent of AWP for each HCPCS-coded drug. Because one HCPCS code may have multiple NDCs that match the HCPCS-coded product's definition, the carriers may determine the Medicare payment by analyzing multiple NDCs.¹⁶

Drug Supply Chain Involves Multiple Parties and Arrangements That Influence the Net Cost to the End Purchaser

Pharmaceutical sales and distribution networks can involve multiple entities and purchasing arrangements that affect the actual acquisition price of the drug for the end purchaser that supplies it to a Medicare beneficiary. Physicians and pharmacies can purchase the kinds of drugs covered under Medicare part B from general or specialty pharmaceutical wholesalers or they can have direct purchase agreements with manufacturers. Purchasers may belong to GPOs that pool the purchasing of multiple entities and negotiate prices with wholesalers or manufacturers. GPOs may negotiate different prices for a drug for different end users, such as physicians, pharmacies, or hospitals.

Determining physicians' or other providers' actual acquisition cost of drugs is complicated by certain practices in the pharmaceutical marketplace that may result in transaction prices paid at the time of sale that do not reflect the final net cost to the purchaser. For example, manufacturers or wholesalers may offer purchasers rebates based on the volume of products purchased. In addition, manufacturers may establish "chargeback" arrangements for end purchasers, under which the purchaser negotiates a price with the manufacturer that is lower than the price the wholesaler charges for the product. The wholesaler sells the product to the purchaser for the lower price negotiated with the manufacturer, and then asks the manufacturer to pay back the difference between the wholesaler's price and the negotiated price.

¹⁶For single-source drugs (drugs whose manufacturer is the sole source for a given product), Medicare's payment is 95 percent of the drug's AWP. For multisource drugs (drugs with generic equivalents or drugs for which there are two or more competing brand-name products), the payment allowance is 95 percent of the lower of (1) the median AWP of all generic forms of the drug or (2) the lowest brand-name product AWP. Within these guidelines, each carrier contracting with Medicare to process claims has discretion to determine which NDCs should be used to calculate the payment rate for each HCPCS code. This can lead to variation in payment amounts among carriers for the same HCPCS-coded drug. By October 1, 2002, all payers, including Medicare, will be required to process and pay drug claims by NDC, rather than HCPCS code, in compliance with the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191). 65 Fed. Reg. 50312, 50370 (to be codified at 42 C.F.R. 162.1002(c)).

Physicians Can Obtain Drugs Covered Under Part B for Significantly Less Than Medicare Payments

Physicians are able to obtain drugs at prices significantly below current Medicare reimbursements. The widely available prices available from wholesalers and GPOs for physician-administered drugs we examined were considerably less than AWP used to establish the Medicare payment. For most of the high-expenditure or high-volume physician-administered drugs we studied and for which we obtained price data, the average widely available discounts from AWP ranged from 13 percent to 34 percent; but two drugs exhibited considerably larger discounts. Physicians we identified as low-volume billers for oncology drugs can also purchase drugs for considerably less than Medicare's payment. In addition to reimbursement for drugs, physicians are paid separately for services associated with drug administration under the Medicare physician fee schedule. In a separate forthcoming report, we find that Medicare's basic method for calculating these payments is sound, but it deviated from this method in calculating payments for certain services, including chemotherapy administration.¹⁷ We also find that oncologists' payments relative to their estimated practice expenses are close to the average for all specialties. In that report, we make recommendations to improve Medicare physician payments for all services.

Physicians' Drug Acquisition Costs Are Generally Lower Than AWP-Based Medicare Payment

Among the 31 drugs we analyzed, which accounted for the majority of Medicare spending and volume, 21 were provided almost exclusively by physicians. Physicians providing drugs to treat cancer—the specialties of hematology/oncology, medical oncology, and urology—account for most Medicare claims for 19 of these drugs.¹⁸ Oncologists and groups representing oncologists told us that oncologists can purchase Medicare-covered drugs for less than the Medicare payment amount. Price lists from wholesalers and GPOs show that widely available prices were considerably less than AWP used to establish the Medicare payment for 18 of these physician-administered cancer drugs, with price information unavailable for one other. (See table 4.) For 16 of the cancer drugs, the average discount from AWP ranged from 13 percent to 34 percent, and two drugs exhibited considerably larger discounts. Prices were available for only one of the two noncancer drugs generally provided by physicians, and

¹⁷See our forthcoming report *Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements* (GAO-02-53, October 2001).

¹⁸Of the other high-volume/high-expenditure drugs we analyzed, orthopedic surgeons and neurologists were each the primary billers for a single product.

its average discount from AWP was 18 percent. Certain purchasers may have access to even greater discounts for certain products than the widely available discounts we report here.

Table 4: Widely Available Discounts From AWP for Medicare-Covered Drugs Billed Primarily by Physicians, 2001

Drug name	Specialty most frequently billing for drug	Average AWP ^a	Average widely available discount from AWP (percentage) ^b
Leuprolide acetate (for depot suspension)	urology	\$618.93	17.6
Rituximab	oncology ^c	\$478.47	19.2
Goserelin acetate implant	urology	\$469.99	21.9
Docetaxel	oncology	\$313.51	22.0
Filgrastim (G-CSF) 480 mcg	oncology	\$300.40	18.0 ^d
Pamidronate disodium	oncology	\$279.86	16.8
Hylan G-F 20	orthopedic surgery	\$225.13	17.7 ^d
Filgrastim (G-CSF) 300mcg	oncology	\$193.62	18.4 ^d
Paclitaxel	oncology	\$180.57	19.0
Irinotecan	oncology	\$141.32	22.9
Carboplatin	oncology	\$120.48	20.3
Gemcitabine HCl	oncology	\$112.34	21.3
Dolasetron mesylate, injection	oncology	\$45.02	65.0 ^d
Granisetron HCl, injection	oncology	\$19.52	29.3
Leucovorin calcium	oncology	\$18.44	85.6
Epoetin alpha for non-ESRD use	oncology	\$12.91	15.2
Ondansetron HCl, injection	oncology	\$6.41	12.8
Botulinum toxin type A	neurology	\$4.86	n/a ^e
Imiglucerase	oncology	\$3.95	n/a ^e
Dexamethasone sodium phosphate	oncology	\$1.44	14.2
Heparin sodium	oncology	\$0.43	34.4

^a"Average AWP" is the average of AWP of each NDC for that product adjusted to the HCPCS-defined dosage.

^b"Average widely available discount from AWP" for each drug was calculated by (1) determining the average widely available price(s) for each NDC for that drug, (2) determining the percentage difference between the average widely available price(s) and the AWP for each NDC for that drug, and (3) averaging the percentage differences for all NDCs for that drug.

^c"Oncology" specialty includes hematology/oncology and medical oncology.

¹⁸Average widely available discount from AWP¹⁸ in 2001 for this drug is based on a price or prices from a single wholesaler. For these four drugs, we had 2000 data from two or more sources. Those data showed that the average widely available discount from AWP in 2000 was 18.8 percent for Filgrastim (G-CSF) 480 mcg, 17.6 percent for Hylan G-F 20, 19.0 percent for Filgrastim (G-CSF) 300mcg, and 42.2 percent for Dolasetron mesylate, injection.

¹⁹We were unable to obtain wholesaler or GPO prices for these products.

Source: GAO analysis of data from BESS, the Medical Economics Drug Topics Red Book CD-ROM vol. 21, and wholesaler and GPO price lists.

While physician practices that purchase large volumes of drugs may have access to larger discounts and rebates, low-volume providers can also purchase drugs for markedly less than AWP, and often at additional discounts below widely available prices.¹⁹ (See table 5.) Our survey of physicians who billed Medicare for low volumes of cancer drugs indicated they received discounts that were as large as or larger than widely available discounts for 11 of the 16 products for which they were able to provide price information, although these discounts may not be as high as those obtained by higher-volume purchasers. These practices reported a variety of arrangements for obtaining these drugs, including contracts with manufacturers, wholesalers, or GPOs.

¹⁹For example, physicians and other purchasers can obtain lower prices if they make prompt payments.

Table 5: Discounts From AWP Obtained by Physicians Who Billed Medicare for a Low Volume of Selected Drugs, Compared to Widely Available Discounts, 2001

Drug name	Low volume billers' average discount from AWP (percentage)	Average widely available discount from AWP^a (percentage)
Leuprolide acetate (for depot suspension)	32.8	17.6
Rituximab	15.7	19.2
Goserelin acetate implant	22.3 ^b	21.9
Docetaxel	22.0	22.0
Filgrastim (G-CSF) (480 mcg)	22.4	18.0 ^c
Pamidronate disodium	18.0	16.8
Filgrastim (G-CSF) (300 mcg)	21.7	18.4 ^c
Paclitaxel	25.8	19.0
Irinotecan	27.1	22.9
Carboplatin	20.0 ^b	20.3
Gemcitabine HCl	16.1	21.3
Dolasetron mesylate, injection	62.0	65.0 ^c
Granisetron HCl, injection	28.1	29.3
Leucovorin calcium	90.4	85.6
Epoetin alpha for non-ESRD use	22.1	15.2
Ondansetron HCl, injection	26.4	12.8

^a"Average widely available discount from AWP" for each drug was calculated by (1) determining the average widely available price(s) for each NDC for that drug, (2) determining the percentage difference between the average widely available price(s) and the AWP for each NDC for that drug, and (3) averaging the percentage differences for all NDCs for that drug.

^b"Low-volume billers' average discount from AWP" for this drug is based on a price from a single physician.

^c"Average widely available discount from AWP" for this drug is based on a price or prices from a single wholesaler.

Notes: Out of our sample of 108 physicians, 14 provided us with acquisition cost data for 16 of the 18 cancer treatment drugs we examined. An additional 37 physicians belonged to large, hospital-based or national chain oncology practices that likely had access to widely available drug price discounts. Fifty-six physicians could not be contacted or refused to participate. One physician in the sample did not purchase drugs.

Source: GAO telephone survey of a sample of physicians who billed Medicare for a low volume of cancer drugs in 1999 and AWP's listed in a contemporaneous wholesaler catalog.

Medicare Pays Physicians for Drug Administration Through the Physician Fee Schedule

In addition to the AWP-based payment for the drug, physicians receive a payment based on Medicare's physician fee schedule for administering the drug. The physician fee schedule consists of three components: one to account for physician time and effort to provide the service, one for the expenses of operating the physician practice (including payments reflecting the costs of nonphysician personnel involved in the delivery of services), and one for malpractice expenses. The practice expense

component was developed with the best available physician-reported data on the actual costs of running their practices. These costs were then allocated to individual services that are provided and billed for, such as office visits and medical procedures.

Oncologists have expressed concerns that certain costs necessary to administer drugs are not fully reimbursed by the practice expense component of Medicare's physician fee schedule payment. Their representatives told us that certain costs were not reflected in the data originally used to set physician fee schedule payments for drug administration, as changes have occurred in how services are delivered over time. Oncology representatives also indicate concern about the representativeness of the data used to construct the fee schedule. They believe the sample of physician practices that supplied the practice expense data may have been biased by including too many hospital-based oncologists or surgical oncologists, which would understate the practice expenses for chemotherapy services. In addition, the number of oncology practices in the sample is small, increasing the risk that the sample information is not representative.²⁰

We have reported previously that the basic methodology for determining physicians' practice expense payments is reasonable.²¹ In a separate forthcoming report, we examine the adequacy of these payments for oncologists. We find that HCFA deviated from the basic methodology for determining practice expense payments for certain services, including chemotherapy administration by nonphysicians. The use of the alternative methodology resulted in a significant reduction in chemotherapy administration service payments compared to what payments would have been had they been calculated under the basic methodology. However, even with this alternative methodology, oncologists' average practice expense payments in 2001 are 8 percent higher than what they would have been had charge-based payments continued. Further, under the current practice expense methodology, oncologists' payments relative to their estimated practice expenses are close to the average payment for all

²⁰In another study, also mandated by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (see P.L. 106-554, Appendix F., Sec. 411, 114 Stat. 2763, 2763A-508), we are examining methods CMS may use to collect and employ more current information to modify the physician fee schedule to reflect potential changes in service delivery or costs and more representative data on practice expenses.

²¹See *Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term* (GAO/HEHS-99-30, February 24, 1999).

specialties. In the separate report, we make recommendations to improve the appropriateness of Medicare physician fee schedule payments for all services.²²

Medicare Drug Payments Also Substantially Higher Than Costs for Pharmacy Supplier-Billed Drugs

Pharmacy suppliers can also obtain drugs such as those administered through the DME benefit at prices far lower than Medicare payment levels. Pharmacy suppliers were the predominant billers for 10 of the drugs in our sample of high-expenditure and high-volume drugs; these drugs included inhalation therapy drugs administered through DME and oral immunosuppressive drugs. Pharmacy suppliers may also administer infusion drugs, such as chemotherapy drugs in the home setting.²³ For the inhalation therapy drugs, wholesaler and GPO prices that would be generally available to these suppliers for drugs administered through DME were considerably less than AWP prices used to establish the Medicare payment. Wholesaler or GPO price discount information for two of the oral immunosuppressive drugs in our sample was not available, but retail prices for these products from Internet pharmacies were generally below Medicare payment levels. Medicare makes an additional payment for dispensing drugs used in inhalation therapy, but not for drugs used in infusion treatments. Further, Medicare makes a separate payment to DME suppliers for the rental or purchase of the equipment needed to administer the drug, such as nebulizers or infusion pumps, in addition to the payment to the pharmacy supplier for the drug itself. There has been no recent analysis of Medicare's payments relative to the costs for DME used to administer drugs.

²²See our forthcoming report *Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements* (GAO-02-53, October 2001).

²³Like inhalation therapy, infusion therapy, such as therapy for heart failure, can be provided in the home setting using an infusion pump. Infusion therapy involves injection of drugs over time, most often intravenously; Medicare covers infusion pumps and necessary drugs and supplies when it is medically necessary to administer the drug with a durable infusion pump that regulates the rate of infusion. Infusion drugs provided by pharmacy suppliers did not appear as high-volume or high-expenditure products and make up a small percentage of pharmacy suppliers' aggregate Medicare billing. The 10 drugs on our list provided primarily by pharmacy suppliers accounted for 91 percent of their Medicare payments and 98 percent of their Medicare volume in 1999.

Pharmacy Suppliers' Drug Acquisition Costs Are Generally Lower Than AWP-Based Medicare Payment

Pharmacy suppliers were the dominant billers for 10 of the highest expenditure or volume drugs paid for under Medicare part B. Among these 10 drugs were five inhalation therapy drugs and four oral immunosuppressive drugs.²⁴ Prices available from wholesalers and GPOs were much less than the AWP used to establish the Medicare payment for the inhalation therapy drugs. (See table 6.) The average discount from AWP in 2001 ranged from 69 percent to 85 percent. These results were consistent with prior studies of the acquisition costs of similar drugs.²⁵ Widely available wholesale or GPO prices for two of the oral immunosuppressive drugs involved average discounts from AWP of 14 percent and 77 percent. Although we were unable to obtain 2001 price discount information for two other oral immunosuppressive drugs, a review of prices available from Internet pharmacies found that retail prices available for these products were 13 percent and 8 percent below AWP.

²⁴Sterile saline is the tenth.

²⁵IHS OIG, *Medicare Reimbursement of Albuterol* (OEI-03-00-00311), June 2000, and *Medicare Reimbursement of Prescription Drugs* (OEI-03-00-00310), January 2001.

Table 6: Discounts From AWP for Medicare-Covered Drugs Billed Primarily by DME Pharmacy Suppliers, 2001

Drug name	Mode of administration	Average AWP ^a	Average widely available discount from AWP (percentage) ^b
Ipratropium bromide, unit dose form	inhalation	\$3.52	78.0 ^c
Acetylcysteine, unit dose form	inhalation	\$0.67	71.8 ^d
Albuterol, unit dose form	inhalation	\$0.50	85.0
Cromolyn sodium, unit dose form	inhalation	\$0.38	69.1
Albuterol, concentrate	inhalation	\$0.15	n/a ^e
Tacrolimus	oral	\$3.10	n/a ^e
Mycophenolate mofetil	oral	\$2.53	14.2 ^d
Cyclosporine	oral	\$1.55	n/a ^e
Prednisone	oral	\$0.15	76.7 ^c
Saline solution, sterile	intravenous, other	\$0.71	n/a ^e

^a"Average AWP" is the average of the AWP of each NDC for that product adjusted to the HCPCS-defined dosage.

^b"Average widely available discount from AWP" for each drug was calculated by (1) determining the average widely available price(s) for each NDC for that drug, (2) determining the percentage difference between the average widely available price(s) and the AWP for each NDC for that drug, and (3) averaging the percentage differences for all NDCs for that drug.

^c"Average discount from AWP" in 2001 for this drug is based on a price from a single wholesaler. For Ipratropium bromide, unit dose form, we had 2000 data from three sources. Those data showed that the average widely available discount from AWP in 2000 was 66.7 percent. For Prednisone we also had 2000 data from only one source.

^d"Average discounts from AWP were not available for 2001; average discounts are from 2000.

^e"Wholesaler or GPO prices for these products were not available.

Source: GAO analysis of data from BESS, the Medical Economics Drug Topics Red Book CD-ROM vol. 21, and wholesaler and GPO price lists.

Medicare's Payments to Pharmacy Suppliers for Dispensing Drugs Vary by Class of Drug

Medicare's coverage of most drugs provided by pharmacy suppliers is established through the DME benefit; Medicare also covers selected immunizations and certain drugs that can be self-administered, such as blood clotting factors and some oral drugs used in association with cancer treatment and immunosuppressive therapy. The DME benefit covers equipment, such as nebulizers used to administer inhalation therapy drugs for treating respiratory conditions or infusion pumps used to administer

intravenous drugs, and the supplies and drugs used with it. Medicare also covers and makes a separate payment for drugs and supplies used in conjunction with covered DME.²⁶ Medicare uses a fee schedule to pay for most DME. DME fees, which are state specific, are based on historical average supplier charges that are adjusted for inflation over time and are subject to national minimum and maximum payment limits. Medicare pays for certain DME on a monthly basis, subject to a maximum number of months, depending upon whether the equipment is rented or purchased.²⁷

Medicare pays a dispensing fee in conjunction with inhalation therapy drugs used in nebulizers, which account for the majority of Medicare volume and spending in the home setting. In 2000, these dispensing fees amounted to over \$15 million for 3 million billed dispensing services.²⁸ Pharmacy suppliers in aggregate received the bulk of their Medicare payments for dispensing the inhalation therapy drugs we analyzed. Unlike many private payers and most state Medicaid programs, Medicare does not pay a dispensing fee to pharmacists or other providers who supply oral drugs. Finally, Medicare neither covers nor reimburses pharmacy suppliers for the costs of clinical services related to providing infusion therapy drugs. We did not analyze the costs of infusion therapy drugs provided in the home setting because they do not account for a substantial share of Medicare drug spending or volume. DME pharmacy suppliers argued that they provide home infusion services to beneficiaries who are too frail to travel to their physicians' offices for care and need these services in the home. However, such beneficiaries would likely qualify for skilled nursing care under Medicare's home health benefit—designed to

²⁶The DME benefit allows for coverage of DME itself plus "supplies," including drugs that "must be put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment or to assure the proper functioning of the equipment." (See *Medicare Carriers Manual*, Part 3, Chapter II—Coverage and Limitations, section 2100.5, Rev. 1564/pp. 2-45.)

²⁷Medicare will make a maximum of 15 monthly payments if the equipment is rented and 13 monthly payments if it is purchased. There are no limits, however, on how long Medicare will pay for one category of nebulizers that requires frequent servicing as long as the equipment is medically necessary.

²⁸Pharmacy suppliers bill Medicare for each month of providing nebulizer drugs to a beneficiary, regardless of the amount of the drug billed, using HCPCS code E0590. The average dispensing fee is currently \$5.00 per month of service.

provide clinical care with adequate supervision—which could cover such service costs.²⁹

Pharmacy suppliers and their representatives said that the profit on the Medicare drug payment is needed to compensate them for their costs related to inhalation and infusion therapy that are not explicitly covered by Medicare. According to these suppliers, these costs include purchasing drugs; all clinical, administrative, and other labor associated with delivering the drugs; billing and collection; facility and employee accreditation; licensing and certifications; and providing printed patient education materials. They said they are currently able to provide these services to Medicare beneficiaries because of their margin on the Medicare drug payments. Suppliers of inhalation and infusion therapies that we spoke with were unable to quantify the costs of these services specific to the provision of drugs or to the different courses of therapy they provide relative to Medicare's total payment, and we did not identify any other such relevant analysis. Suppliers and their representatives reported to us that the suppliers' acquisition cost of the drug is only a "nominal" portion of the total cost of providing infusion and inhalation therapy to Medicare patients. Specifically, they indicated that drugs represented roughly a quarter of the total cost of inhalation therapy, and approximately 40 percent of the cost of infusion therapy, excluding the cost of DME.

In this work, we did not analyze suppliers' costs of supplying DME relative to Medicare's payment to assess whether those payments also include a profit. However, a prior GAO report indicated two underlying problems with Medicare's fees for DME that could lead to inappropriately high payments.³⁰ First, Medicare does not know what specific products it pays for when its claims administration contractors process claims for DME. DME products with similar functions or purposes are grouped together, with Medicare paying the same amount for any product in the group. These groups of DME products often represent a broad range of product types, quality, and market prices, but claims only indicate a product's group and not the specific item. The second underlying problem with

²⁹Medicare's home health care benefit enables certain beneficiaries with post-acute-care needs and chronic conditions to receive care in their homes. For beneficiaries who qualify, Medicare will pay for skilled nursing, therapy, and home health aide visits under the home health benefit. See *Medicare Home Health Care: Prospective Payment System Could Reverse Recent Declines in Spending* (GAO/HEHS-00-176, September 8, 2000).

³⁰See *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies* (GAO/HEHS-98-102, May 12, 1998).

Medicare's DME payment system is that the fee schedule allowances for DME are often out of line with current market prices. Until recently, the process for adjusting DME payments was very cumbersome. Medicare contractor representatives told us that they do not change the fee schedule allowances to reflect market prices for DME; rather the fees are typically only adjusted for inflation annually. As a result, payment levels may not reflect changes in technology and other factors that could significantly affect market prices.

Private Payers Negotiate Prices, Other Public Payers Rely on Market-Based Benchmarks to Establish Payments for Drugs

Private and public payers use a variety of mechanisms to determine payments for drugs and their administration. Although varied, these mechanisms can generally be categorized as negotiated or contracted prices and fee schedules based on reference or benchmark prices. Private payers can negotiate with pharmacies, other suppliers, and manufacturers, either directly or through agents, to secure discounted prices and rebates that are often based on volume or market share. They or their agents also may negotiate with providers and suppliers to establish payments for services related to providing drugs. Some public programs, such as VA, can purchase drugs at FSS prices, which are linked to market prices. State Medicaid programs often use fee schedules based on AWP or wholesale acquisition cost (WAC) to reimburse providers for outpatient drugs provided under their prescription drug benefit, but receive statutorily guaranteed manufacturers' rebates on drugs that are derived from actual transaction data. The rebates are based in part on AMP. In contrast to Medicare's payment for drugs, both the FSS and the AMP are determined under a statutory methodology and are based on actual market prices that can be verified. In some instances, VA and Medicare have also achieved savings by setting prices through competition.

Private Sector Purchasers Use Contracting and Market Power to Purchase Drugs

Large private health plans or their agents typically negotiate with providers the terms and conditions of payments for drugs and their delivery or administration. In general, private health plans may negotiate with preferred or network providers to establish payments for physician-provided drugs.³¹ Managed care plans reported that the terms of their provider contracts vary considerably. Under some contracts, the plan may

³¹Private health plans may designate a group of preferred or network providers to deliver services to plan beneficiaries for specified payments. With some health plans, beneficiaries may obtain services from another provider but may then be liable for the difference between what that provider charges and what the plan pays.

pay the physician a specified fee for the drug and its administration. Under others, the plan may pay participating physicians a capitated rate, placing them at financial risk for costs of a range of services, including physician-supplied drugs and their administration.

A large health-plan-owned pharmacy supplier reported a somewhat different arrangement. It buys injectible drugs directly from manufacturers and wholesalers and supplies them to the plan's physicians. The plan contracts to pay the physicians separately for administering the drugs. The plan's pharmacy benefits manager told us that the plan became a more aggressive purchaser of physician-provided drugs when it appeared that physicians were being overpaid for these products under an AWP-based reimbursement system. For drugs administered through DME, representatives of infusion and inhalation therapy providers indicated that while some plans may pay an all-inclusive global fee for these therapies, the most common arrangement is for private health plans to make per diem payments for pharmacy services and delivery and separate payments for the drug and nursing services, which, under certain conditions, Medicare covers under the home health benefit.

Private health plans commonly contract with pharmacy benefits managers (PBM) to manage their outpatient drugs dispensed through a retail or mail order pharmacy. PBMs negotiate contracts with retail pharmacies, which usually include discounted prices for the drugs and fees for dispensing the drugs. PBMs may obtain rebates from drug manufacturers. These discounts or rebates are often based on the volume of individual drugs purchased and may be independent of the arrangements between plans and the third parties supplying drugs to beneficiaries such as physicians or pharmacies. Plans often use formularies, lists of preferred drugs that may have lower beneficiary cost sharing, as a means of increasing use of selected drugs.³²

³²Formularies are lists of prescription drugs, grouped by therapeutic class, that health plans or insurers prefer and may encourage physicians to prescribe and beneficiaries to use. A particular product may be included on a formulary because of its medical value or because a favorable price was negotiated with the manufacturer.

Other Public Programs Use Market-Based Reference Prices and Competition to Establish Payments or Rebates

The FSS for pharmaceuticals, administered by VA, is a list of products and their prices available to federal entities that purchase prescription drugs. Manufacturers must agree to supply drugs at these prices in order to have their products covered and paid for by Medicaid programs. The FSS price is intended to equal or better the price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions.³³ To determine the most-favored customer price, manufacturers provide VA information on price discounts and rebates offered to domestic customers and the terms and conditions involved,³⁴ such as length of contract periods and ordering and delivery practices.³⁵ The information used to determine the FSS price is reviewed by VA's OIG. Agencies using the FSS generally provide drugs directly to beneficiaries through their own pharmacies and facilities.

Medicaid programs act as third-party payers, like Medicare, in reimbursing physicians and pharmacies for drugs. Most Medicaid programs reimburse pharmacies using formulas based on a percentage discount from AWP plus a dispensing fee or a percentage markup over WAC plus a dispensing fee.³⁶ WAC is the list price a wholesaler pays to a manufacturer, but it does not include discounts that may affect the net price. WAC is not defined in law, and like AWP is determined by the manufacturer. Medicaid programs receive rebates based on net market prices. Under a provision of the Social Security Act added by the Omnibus Budget Reconciliation Act of 1990 (OBRA), Medicaid programs receive a rebate from manufacturers based on either AMP or the manufacturer's "best price" to a private purchaser.³⁷ AMP is defined in federal law as the average price (including cash discounts and other price reductions) paid to drug manufacturers by

³³48 C.F.R. Sec. 538.270.

³⁴48 C.F.R. Sec. 538.270.

³⁵Because the terms and conditions of commercial sales vary, there may be legitimate reasons why the government does not always obtain the most-favored customer price. Hence, under the General Services Administration regulations, VA may accept a higher price if it determines that (1) the price offered to the government is fair and reasonable and (2) awarding the contract is otherwise in the best interest of the government.

³⁶Medicaid dispensing fees ranged from \$2 to over \$6 per prescription in 2000. PBMs at private health plans can negotiate even lower dispensing fees that plans pay pharmacies through their ability to restrict their pharmacy networks.

³⁷Section 1927 of the Social Security Act, added by OBRA 1990, P.L. 101-508, Section 4401, 104 Stat. 1388, 1388-143(1990) (classified to 42 U.S.C. Sec. 1396r-8).

U.S. wholesalers for drugs distributed to the “retail class of trade.”³⁸ AMP is thus a measure of actual transaction prices between wholesalers and manufacturers. “Best price” is also defined in federal law as the lowest price (including cash discounts and other price reductions) available from the manufacturer to any U.S. wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity, with some exceptions. Manufacturers currently report AMPs and “best prices” to CMS in order to participate in Medicaid. CMS can survey manufacturers’ sales information to ensure that AMP and “best price” computations are correct. However, the Social Security Act requires that CMS maintain the confidentiality of this pricing information and it is therefore not publicly available.

Public payers have made several attempts to use competition to obtain more favorable prices for drugs. VA has used a competitive bidding process to obtain national contracts for selected drugs at prices that are even lower than FSS prices. VA identified drugs regarded as therapeutically equivalent and sought contracts from manufacturers for low prices in exchange for VA including only one drug of each type on its national formulary. VA contract prices in 2000 averaged 33 percent lower than corresponding FSS prices.

The Balanced Budget Act of 1997 authorized HCFA to conduct several limited-scale demonstration projects to evaluate competitive bidding’s applicability to the Medicare program. In one of these demonstration projects currently under way in San Antonio, Texas, suppliers bid to provide inhalation drugs, such as albuterol, to Medicare beneficiaries. While Medicare normally allows any qualified provider to participate in the program, under the demonstration only those 11 bidders that were selected can participate. In exchange for restricting their choice of providers, beneficiaries have no liability for differences between what suppliers charge and what Medicare pays. Preliminary CMS information suggests savings of approximately 26 percent on these inhalation drugs in the San Antonio competitive bidding demonstration.

Conclusions

Medicare’s method for establishing drug payment levels is flawed. In tying its payment to AWP, a price that may be neither an average nor what wholesalers charge, Medicare has been paying much more than providers’

³⁸Section 1927(k)(1) of the Social Security Act (classified to 42 U.S.C. Sec. 1396r-8(k)(1)).

likely acquisition costs. Medicare's AWP-based methodology does not incorporate information on actual transaction prices, such as that used by VA in establishing FSS prices or the AMPs used to calculate Medicaid drug rebates.

Our findings strongly suggest that Medicare should revise its drug payment policies. Payments for the drugs themselves should closely parallel market prices that providers pay to acquire drugs. The program needs to use information on actual market prices net of rebates and discounts, similar to information currently available to VA to establish the FSS and to HHS to determine the Medicaid rebates. Although the widely available prices we report here are often substantially below Medicare's payment, certain providers may be able to obtain even greater discounts. However, the lowest prices, used in setting the FSS prices and Medicaid rebates, may not be available to all Medicare providers for all Medicare-covered drugs. To better ensure that beneficiary access is not compromised, in setting payment levels it is important to be mindful that providers' ability to secure discounts likely varies.

Physicians and other providers acknowledge that payments for drugs are higher than their costs, but contend that profits on the drugs compensate for what they regard as underpayments for their administration. It should be a principle of Medicare payment policy to pay for each service appropriately and not to rely on potential overpayments for some services to offset potential inadequate payments for complementary services. Consequently, separate payments for administration and delivery should be made, with those payments appropriately reflecting the variation associated with how the drugs are provided. Hence, different methods of determining drug delivery and administration payments may be necessary for different types of drugs.

Some benefits of competition for securing selected drugs under certain circumstances have been demonstrated by VA and by Medicare in the San Antonio demonstration. Medicare's experience is rather limited and involves a very small number of drugs. Nevertheless, how the use of competitive bidding might be expanded without compromising beneficiary access is worth exploring.

Recommendations for Executive Action

In order to improve the accuracy of Medicare payments for drugs and related services, we are recommending that the Administrator of CMS take the following actions.

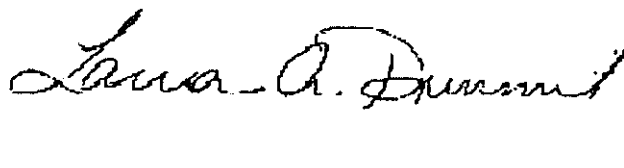
- Establish Medicare payment levels for part-B prescription drugs and their delivery and administration that are more closely related to their costs. Payments for drugs should be set at levels that reflect actual market transaction prices and the likely acquisition cost to providers. To accomplish this, the Administrator should consider how information on market transactions already available to HHS or VA may be used as a benchmark for Medicare payment levels. If the Administrator determines that legislative action would be required to use such information in setting Medicare reimbursements, he should seek this action immediately.
- Examine the benefits and risks of expanding the current competitive bidding demonstration projects for drugs covered under part B.
- Institute a process to monitor access to Medicare part B-covered drugs to ensure that payment changes do not negatively affect access for particular drugs, or groups of beneficiaries or in certain geographic areas.

Agency Comments

CMS noted that our findings confirmed the results of studies by the HHS OIG that indicated that Medicare payments for drugs are substantially higher than their actual acquisition costs. CMS agreed that Medicare should appropriately pay for both part B-covered drugs and the services required to furnish them. CMS's comments appear in their entirety as appendix II.

We are sending copies of this report to the Administrator of CMS and interested congressional committees. We will make copies available to others on request.

If you or your staffs have any questions about this report, please call me at (202) 512-7119 or James Mathews at (202) 512-9427. Major contributors to this report were Ginny Hsieh, Dina Kirschenbaum, Kathryn Linehan, and Theresa Thompson.



Laura A. Dummit
Director, Health Care—Medicare Payment Issues

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Appendix I: Scope and Methodology

In conducting this study, we interviewed officials at CMS, VA, HHS OIG, and DOJ. We also interviewed and solicited information about drug acquisition costs and costs related to drug administration from professional associations representing physicians and other providers with a major stake in our evaluation. We requested price data on specific drugs from major pharmaceutical wholesalers, oncology specialty wholesalers, and GPOs, none of which responded to our request by the time we finalized this report. We also requested price data from specialty pharmacies, DME pharmacy suppliers, a national oncology clinic chain, and physicians, including physicians we identified as billing for low volumes of Medicare-covered drugs. We interviewed representatives from large managed care organizations and their agents regarding the methods they used to purchase or pay for pharmaceuticals as well as the purchase prices they were able to obtain. We also interviewed staff at the companies that publish major price reporting compendia that collect and report average wholesale prices for drugs. We conducted quantitative analyses using data from CMS and other sources. We did our work in accordance with generally accepted government auditing standards from January through September 2001.

To determine the drugs and biological products that accounted for the most Medicare spending and volume, we used 1999 data from BESS. We also used BESS data to determine spending and volume by part B carrier, place of service, and specialty. All analyses using BESS data excluded data on services supplied in Puerto Rico and the U.S. Virgin Islands and payments made on behalf of the Railroad Retirement Board.

We excluded four HCPCS-coded products from our analysis because of problems obtaining accurate pricing information or, in one case, because the code was not specific enough to link to a given product. From the high-volume/high-expenditure HCPCS codes that were chosen for our study, we evaluated pricing information for the NDCs that were used to determine reimbursement rates for that HCPCS. We asked the Medicare part B carriers with the highest allowed drug charges in each region and the DME regional carriers to provide the NDCs they used to calculate reimbursement for 31 HCPCS codes. Because carriers may use somewhat different groups of NDCs, we included all of the NDCs in our analysis of prices for each HCPCS we analyzed.

We obtained widely available drug prices for selected HCPCS for 2000 and 2001 from several wholesalers' and GPOs' price lists, which we obtained from a government agency and from providers. The AWP's were obtained

Appendix I: Scope and Methodology

from the 2000 Drug Topics' Red Book and the 2001 Drug Topics' Red Book CD-ROM by NDC for each year.

To identify physicians who billed for low volumes of multiple drugs, we examined all Medicare part B drug claims from 1999 and identified 1,115 physicians who met our definition of a low-volume Medicare biller for cancer drugs in 1999, and selected a random sample of 108 physicians. We defined low-volume biller as a physician who billed for between the 10th and 25th percentile of total allowed units for three or more of the following drugs: Dexamethasone sodium phosphate, Leuprolide acetate, Rituximab, Goserelin acetate, Docetaxel, Filgrastim (480 mcg), Pamidronate disodium, Filgrastim (300 mcg), Paclitaxel, Irinotecan, Carboplatin, Gemcitabine HCl, Dolasetron mesylate, Granisetron HCl, Leucovorin calcium, Epoetin alpha for non-ESRD use, and Ondansetron HCl. We then merged the claims file physician sample with the Unique Physician Identification Number directory to get names and addresses of providers. We received 74 prices for NDCs for 16 HCPCS-coded drugs from 14 low-volume billers. An additional 37 physicians were hospital-based, operated out of large practices, or worked for large nationally owned chain oncology practices. We could not contact 36 physicians for whom we could not find correct telephone numbers. Twenty practices declined to provide us with information or did not provide information in time to be included in this report. One practice indicated it did not purchase drugs.

Appendix II: Comments From the Centers for Medicare and Medicaid Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: SEP 19 2001

TO: Laura A. Dunmilt
Director, Health Care—Medicare Payment Issues
General Accounting Office

FROM: Thomas A. Scully *T. A. Scully*
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: General Accounting Office (GAO) Draft Report, *MEDICARE: Payments for Covered Drugs Exceed Providers' Costs* (GAO-01-1118)

The GAO confirms the findings of its previous reports along with previous reports from the Office of Inspector General that Medicare's payments for drugs are substantially higher than the actual costs to physicians and other providers acquiring these drugs. Physicians and other providers indicate that while Medicare overpays for the cost of the drugs, Medicare payments sometimes do not adequately compensate for services related to furnishing the drugs.

We agree with GAO that Medicare needs to pay appropriately for all Medicare benefits, including the drugs we currently cover, as well as, the services required to furnish these drugs. We look forward to working with the Congress and GAO to address this important issue.

The Health Care Financing Administration (HCFA) was renamed to the Centers for Medicare & Medicaid Services (CMS). We are exercising fiscal restraint by exhausting our stock of stationery.

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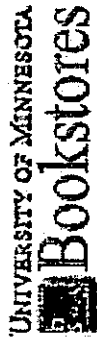
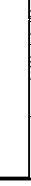
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 - 8:30 a.m. to 5:00 p.m.

Special Summer Session Hours

- June 17-20
 - 8:30 a.m. to 6:00 p.m.

- June 21
 - 8:30 a.m. to 5:00 p.m.

Beginning Monday, June 24

- Monday through Friday
 - 8:30 a.m. to 5:00 p.m.
- Saturday and Sunday
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- May 30-31
 - 8:30 a.m. to 5:00 p.m.
- June 3-7
 - 8:30 a.m. to 5:00 p.m.
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 - 8:30 a.m. to 5:00 p.m.

Special Summer Session Hours

- June 17-20
 - 8:30 a.m. to 6:00 p.m.

- June 21
 - 8:30 a.m. to 5:00 p.m.

Beginning Monday, June 24

- Monday through Friday
 - 8:30 a.m. to 5:00 p.m.
- Saturday and Sunday
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- Saturday and Sunday
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- May 20-22
 - 11:00 a.m. to 1:00 p.m.
- May 23-24
 - 10:00 a.m. to 2:00 p.m.
- May 28
 - 10:00 a.m.-6:00 p.m.
- May 29-30
 - 10:00 a.m. to 2:00 p.m.
- May 31
 - closed
- June 3
 - 10:00 a.m. to 3:00 p.m.
- June 4
 - closed

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Beginning June 5

EXHIBIT 6

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Health, Committee on
Finance, U.S. Senate

For Release on Delivery
Expected at 10:00 a.m.
Thursday, March 14, 2002

MEDICARE OUTPATIENT DRUGS

Program Payments Should Better Reflect Market Prices

Statement of Laura A. Dummit
Director, Health Care—Medicare Payment Issues



Mr. Chairman and Members of the Subcommittee:

I am pleased to be here as you discuss Medicare's payments for covered outpatient prescription drugs. As you know, Medicare pays for only a limited number of outpatient drugs and biologicals—largely those that cannot be self-administered or require certain medical equipment to be administered.¹ The covered drugs are typically provided by a physician, as is the case for chemotherapy drugs, or through pharmacy suppliers, as for respiratory drugs.

Medicare's payments for covered drugs have been scrutinized for several years. Recent studies by the Department of Justice and the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) show that Medicare's payment for covered outpatient drugs in some cases is significantly higher than the actual costs to the physicians and pharmacy suppliers who bill Medicare for them.² Yet attempts to reduce these payments have been met with provider claims that overpayments for the drugs are needed to cover underpayments for administering or delivering them. In September 2000, the Health Care Financing Administration (HCFA)—now the Centers for Medicare and Medicaid Services (CMS)³—took steps to reduce Medicare's payment for covered outpatient drugs by authorizing Medicare carriers, the contractors that pay drug claims, to use prices obtained in Justice Department investigations of providers' drug acquisition costs in setting payment rates. HCFA retracted this authority in November 2000 following concerns raised by providers that reducing Medicare's drug payments could affect beneficiary access to these drugs and related services. In December 2000, as part of recent Medicare legislation,⁴ the Congress directed us to study Medicare's payments for covered outpatient drugs and make recommendations for payment methodology refinements. In September 2001, we reported our

¹For the remainder of this statement, we will refer to "drugs and biologicals" covered under Medicare part B, which generally covers physician and outpatient hospital services, as "outpatient drugs."

²For example, see U.S. Department of Health and Human Services, Office of the Inspector General, *Medicare Reimbursement of Albuterol*, OEI-03-00-00311 (Washington, DC: June 2000) and *Medicare Reimbursement of Prescription Drugs*, OEI-03-00-00310 (Jan. 2001).

³Our statement refers to HCFA when discussing actions taken under that name.

⁴The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. No. 106-554, App. F, 106 Stat. 2763, 2763A-522).

findings and made recommendations.⁵ In October 2001, we also reported on the adequacy of Medicare payments to oncologists for administering chemotherapy drugs as directed by the Congress.⁶

My remarks today will focus on (1) Medicare payment policies for covered outpatient drugs and related services to administer or deliver the drugs and (2) opportunities to improve the appropriateness of Medicare's payments by adapting key features of other federal payers' reimbursement policies. My comments are based primarily on our studies of Medicare payments for covered outpatient drugs and for administering chemotherapy.

In summary, Medicare's payment for covered outpatient drugs is significantly higher than prices widely available to providers. Medicare's method for establishing drug payments is flawed. Medicare pays 95 percent of the average wholesale price (AWP), which, despite its name, is neither an average nor a price that wholesalers charge. Instead, it is a number that manufacturers derive using their own criteria; there are no requirements or conventions that AWP reflect the price of any actual sale of drugs by a manufacturer. Manufacturers report AWP to organizations that publish them in drug price compendia, and Medicare carriers base providers' payments on these published AWP.

We found that widely available prices at which providers could purchase drugs in 2001 were substantially below AWP. For both physician-billed drugs and pharmacy supplier-billed drugs, Medicare payments often far exceeded widely available prices. Despite concerns that the discounts available to large purchasers would not be available to physicians with a small number of drug claims, these physicians with low volumes reported that their purchase prices were the same or less than the widely available prices we documented.

Physicians and pharmacy suppliers contend that the excess payments for covered drugs are necessary to offset what they claim to be

⁵U.S. General Accounting Office, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs*, GAO-01-1118 (Washington, D.C.: Sept. 21, 2001).

⁶This study was mandated in section 213 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. No. 106-113, App. F, 113 Stat. 1501, 1501A-350). See U.S. General Accounting Office, *Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements*, GAO-02-53 (Washington, DC: Oct. 31, 2001).

inappropriately low Medicare payments or no such payments for services related to the administration or delivery of these drugs. For administering physician-billed drugs, such as those used in chemotherapy, Medicare makes explicit payments under the physician fee schedule, typically through the practice expense component of the payment. Our October 2001 report on practice expense payments under the fee schedule showed that, overall, payments to oncologists relative to their estimated practice expenses were comparable to those for all specialties. But we also found that HCFA made inappropriate modifications to its basic method of setting these payments, which resulted in a lowering of the average fees paid for the administration of chemotherapy.

While physicians receive an explicit payment for administering drugs, Medicare's payment policies for delivering pharmacy supplier-billed drugs and related equipment are uneven. Pharmacy suppliers billing Medicare receive a dispensing fee for one drug type—inhalation therapy drugs—but there are no similar payments for the other covered drugs, such as infusion therapy or covered oral drugs. Suppliers do receive an additional Medicare payment for the rental or purchase of durable medical equipment (DME) and related supplies that are used to administer drugs, such as inhalation and infusion therapy, that require DME. However, in 1998 we reported two problems with the program's payments for DME—a wide variety of products may be covered under a single fee and fee schedule allowances were out of line with current market prices.⁷ These problems may result in overpayments that implicitly compensate for some service delivery costs not covered by Medicare.

Other payers and purchasers, such as private health plans and the Department of Veterans Affairs (VA), employ different approaches in paying for or purchasing drugs that may be instructive for Medicare. In particular, VA uses the leverage from the volume of federal drug purchases to secure verifiable data on actual market transactions and it uses the prices paid by manufacturers' best customers to set Federal Supply Schedule (FSS) prices. VA also uses competitive bidding to obtain lower prices for certain products for its own facilities. These approaches may be instructive for Medicare provided that they are adopted in ways that reflect Medicare's unique responsibilities and characteristics.

⁷See U.S. General Accounting Office, *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies*, GAO/HEHS-98-102 (Washington, DC: May 12, 1998).

In our view, Medicare should pay for each service appropriately and not rely on overpayments for some services to offset inadequate payments for complementary services. Our recommendation that Medicare begin to establish payment rates using information about actual market transactions for covered drugs at levels that reflect providers' acquisition costs is consistent with this principle. We have also recommended that the CMS administrator use consistent methods in setting physician practice expense fees for all services, including those for administering chemotherapy.

Background

While the traditional Medicare program does not have a comprehensive outpatient prescription drug benefit, the program does cover roughly 450 outpatient drugs. The outpatient drugs with the highest Medicare payments and billing volume fall into three categories: those that physicians bill for and that are typically provided in a physician office (such as chemotherapy drugs); those that pharmacy suppliers bill for and that are administered through DME, such as a respiratory drug given in conjunction with a nebulizer;⁸ and those that are also billed by pharmacy suppliers but are patient-administered and covered explicitly in statute.⁹ In 1999, spending for Medicare-covered outpatient prescription drugs totaled almost \$4 billion.¹⁰

Small Number of Products Accounts for Majority of Program Spending and Volume

Although Medicare reimburses providers for roughly 450 outpatient drugs, spending is concentrated on a small number of products billed by pharmacy suppliers and a few physician specialties. For example, just 35 drugs accounted for 82 percent of Medicare spending and 95 percent of the claims volume in 1999. These 35 products included certain injectible drugs to treat cancer, inhalation therapy drugs, and oral immunosuppressive drugs, such as those used by organ transplant patients. Physician-billed drugs accounted for the largest share of Medicare program spending, while pharmacy supplier-billed drugs

⁸A nebulizer is a device driven by a compressed air machine. It allows the patient to take medicine in the form of a mist (wet aerosol).

⁹Medicare-covered outpatient drugs that can be self-administered include such drugs as blood clotting factors and some oral drugs used in association with cancer treatment and immunosuppressive therapy.

¹⁰Spending is defined as Medicare's total payment, of which the program's share is 80 percent and the beneficiaries' share is 20 percent.

constituted the largest share of the billing volume. Drugs provided in physician offices accounted for more than 75 percent of total Medicare spending for drugs in 1999 and just three specialties—hematology oncology, medical oncology, and urology—submitted claims for 80 percent of the total physician billings for outpatient drugs. By contrast, pharmacy suppliers accounted for more than 80 percent of Medicare drug billing volume and less than 20 percent of corresponding payments. Two inhalation therapy drugs accounted for 88 percent of the Medicare billing volume for pharmacy-supplied drugs administered in a patient's home.¹¹

**Medicare Payments for
Drugs Are Based on
"Prices" Set by
Manufacturer**

Medicare bases its reimbursements to physicians and other providers for a covered outpatient drug on the product's AWP, with Medicare beneficiaries contributing 20 percent of the payment. The AWP, however, is neither "average" nor "wholesale;" it is simply a number assigned by the product's manufacturer. The AWP is often described as a "list price," "sticker price," or "suggested retail price," reflecting that it is not necessarily the price paid by a purchaser or a consistently low, or "wholesale," price.

Because the term AWP is not defined in law or regulation, the manufacturer is free to set an AWP at any level, regardless of the actual price that purchasers pay. Manufacturers periodically report AWPs to publishers of drug pricing data. While there is no required frequency for manufacturers to report AWPs, most publishers said they attempt to update AWPs at least annually. The Medicare-allowed amount, or payment level, for each HCFA Common Procedure Coding System (HCPCS) -coded drug is 95 percent of its AWP.¹² Given the latitude manufacturers have in setting AWPs, these payments need not be related to market prices that physicians and suppliers actually pay for the products.

¹¹These two drugs are ipratropium bromide and albuterol (unit dose form).

¹²The payment is based on the AWP for all the drugs having the same HCPCS code. A National Drug Code (NDC) identifies an individual drug. The Food and Drug Administration assigns the NDCs, which are the universal product identifiers for drugs for human use. Each NDC specifies a chemical entity, manufacturer, dosage form, strength, and package size. For example, a single drug—marketed by one manufacturer in one form and strength but in three package sizes—would have three NDCs. HCFA defines HCPCS codes, which generally include multiple NDCs. For single-source drugs, Medicare's payment is 95 percent of the drug's AWP. For multisource drugs, generally those available from multiple manufacturers, the payment allowance is 95 percent of the lower of (1) the median AWP of all generic forms of the drug or (2) the lowest brand name product's AWP.

**Varying Payment
Arrangements Affect
Providers' Final Purchase
Price**

Common drug purchasing arrangements can substantially reduce a provider's actual acquisition price for a drug. Physicians and suppliers may belong to group purchasing organizations (GPO) that negotiate prices with wholesalers or manufacturers on behalf of GPO members. GPOs may negotiate different prices for different purchasers, such as physicians, suppliers, or hospitals. In addition, providers can purchase covered outpatient drugs from general or specialty pharmaceutical wholesalers or can have direct purchase agreements with manufacturers. In these arrangements, providers may benefit from transactions, including rebates and "chargebacks" that also reduce the actual costs providers incur. Rebates offered by drug manufacturers or wholesalers may be based on the number of different products purchased over an extended period. Under a chargeback arrangement, the provider negotiates a price with the manufacturer that is lower than the price the wholesaler normally charges for the product, and the provider pays the wholesaler the negotiated price. The manufacturer then pays the wholesaler the difference between the wholesale price and the price negotiated between the manufacturer and provider.

**Medicare's Payment
for Covered
Outpatient Drugs Is
Significantly Higher
than Prices Widely
Available to Providers**

For the outpatient drugs accounting for the bulk of Medicare spending and claims, Medicare payments in 2001 were almost always considerably higher than wholesalers' prices widely available to physicians and suppliers.¹³ This was true regardless of whether there were competing drug products or whether a particular drug was available from only one manufacturer. Physicians who had few Medicare claims for covered drugs were able to obtain these wholesalers' prices or even more favorable prices. Physicians and pharmacy suppliers told us that the higher payments are necessary to cover costs of administering and dispensing their drugs that Medicare does not pay. Our work indicates that CMS's method of computing Medicare fees for physician-administered drug claims, which are submitted primarily by oncologists, inappropriately reduced those fees. Furthermore, Medicare's coverage and payment policies for pharmacy supplier-billed drugs are uneven: Medicare pays a dispensing fee for delivering some pharmacy supplier-billed drugs; for

¹³We attempted to analyze prices for 35 high-volume and high-expenditure outpatient drugs, however, our analysis excluded some high-volume and high-expenditure drugs because of inadequate pricing data. Our results are based on wholesaler and GPO prices for 19 physician-administered drugs and 6 drugs provided primarily by pharmacy suppliers. Volume for a drug is measured in terms of the number of units provided.

others, however, Medicare makes no explicit payment for delivery and administration services.

**Wide Disparities Exist
Between Drug Acquisition
Costs and Medicare
Payments**

Physician-billed drugs account for the bulk of Medicare spending on outpatient drugs. Of those billed by physicians, drugs used to treat cancer accounted for most of Medicare's expenditures. The prices available to physicians through wholesaler and GPO catalogues are far lower than Medicare's payment. The catalogue prices ranged from 13 percent to 34 percent less than AWP for most drugs that we examined and up to 86 percent less for one. These prices indicate that Medicare's payments for physician-administered outpatient drugs were at least \$532 million higher than providers' potential acquisition costs in 2000. Further, the overpayment is likely even greater because additional reductions provided to certain purchasers through chargebacks, rebates, and other discounts drive down the actual acquisition costs to providers even more.

Concerns have been expressed that providers who had few beneficiaries requiring chemotherapy drugs either could not or do not obtain such favorable prices. Therefore, we surveyed a sample of physicians who billed Medicare for low volumes of chemotherapy drugs to see if they were able to obtain discounts similar to those of providers with a high volume of claims. More than one-third of these physicians who billed for a low volume of drugs actually belonged to large, hospital-based, or national chain oncology practices that likely had access to widely available drug discounts. The low-volume providers who responded to our survey reported similar or better discounts than the widely available prices we documented, although these discounts may not be as high as those obtained by high-volume purchasers.

Inhalation therapy drugs administered through DME and oral immunosuppressive drugs represent most of the high-expenditure, high-volume drugs billed to Medicare by pharmacy suppliers. As with physician-billed drugs, Medicare's payments for pharmacy supplier-billed drugs generally far exceeded the prices available to these suppliers. Further, the discounts we found were largest for products that could be obtained from more than one source. Based on the discounts for six drugs billed primarily by pharmacy suppliers, we found that Medicare's payments were at least \$483 million more than what the suppliers potentially paid in 2000. Specifically, two DME-administered drugs, albuterol and ipratropium bromide, that accounted for most of the pharmacy supplier-billed drugs paid for by Medicare were available to pharmacy suppliers at prices that averaged, respectively, 85 percent and 78 percent less than AWP. Two

other high-volume DME-administered drugs had prices averaging 69 percent and 72 percent less than AWP. Two of the high-volume oral immunosuppressives were available from wholesalers with average discounts of 14 percent and 77 percent. Although wholesale price information on the two other oral drugs was not available, retail prices from online pharmacies were as much as 13 percent and 8 percent below AWP.

Based on our findings, we recommended that Medicare revise its drug payment policies to more closely parallel market prices that providers actually pay to acquire drugs. To set such prices, Medicare needs to use information on actual market prices, accounting for rebates and other discounts. It is important in setting payment levels to be mindful that providers' ability to secure discounts likely varies, and that prices need to be sufficient to ensure that beneficiary access is not compromised.

Current Drug Payments Called Necessary to Offset Inadequate Payments for Related Services

Physicians and pharmacy suppliers contend that the excess in Medicare's payments for covered outpatient drugs compensates for related service costs inadequately reimbursed or not explicitly covered at all. Medicare payment policies for administering or delivering a drug vary, depending on who provides the drug to the patient. Physicians are compensated directly for drug administration through the physician fee schedule. Pharmacy suppliers are compensated for dispensing inhalation therapy drugs used with a nebulizer, which make up the majority of their Medicare outpatient drug claims. No explicit payments are made to pharmacy suppliers for dispensing other drugs, but the suppliers receive payments for equipment and supplies associated with DME-administered drugs.

Medicare pays physicians based on a fee schedule that includes rates for administering chemotherapy. Payments for chemotherapy administration are important because chemotherapy drugs represent the bulk of Medicare payments for physician-administered drugs. Medicare's payment for chemotherapy administration is usually determined by the practice expense component of the fee schedule, as there is generally no direct physician involvement with these services.¹⁴ Payments for practice expenses were revised beginning in 1999. These payments, which had

¹⁴Practice expenses include the salaries of nurses, technicians, and administrative staff, and rent, utilities, equipment, and supplies. Practice expenses constitute one of three components in Medicare's physician fee schedule. The other two are the physician work component and the malpractice component.

been based on charges physicians had billed in prior years, were recomputed to reflect the relative resources required to provide each service. Implementation of these resource-based practice expense payments has been controversial. This is in part because the Congress required that payments be budget neutral so that if one specialty's fees increased on average, some others would have to be reduced. Such redistributions have occurred, and some are significant. However, Medicare's physician payments were deemed adequate in the aggregate, as almost all physicians participated in Medicare and accepted the program's fees as payment in full, so that budget neutrality appeared unlikely to cause access problems for beneficiaries.

Oncologists argue that Medicare's payments for administering chemotherapy are inappropriately low and that the excess Medicare drug payments based on the AWP are needed to offset their losses. Yet, oncology is one of the specialties to gain from the introduction of new practice expense payments under the physician fee schedule. In our October 2001 study on physicians' practice expenses under Medicare's fee schedule, we showed that practice expense payments to oncologists were 8 percent higher than they would have been if the prior payment method had been maintained; we also showed that overall oncologists' payments relative to their estimated practice expenses were close to the average for all specialties.

While oncologists do not appear disadvantaged overall under the fee schedule, adjustments that HCFA made to the basic method of computing payments reduced fees for some oncologists' services, particularly chemotherapy administration. In those adjustments, HCFA modified the basic method in computing payments for services delivered without direct physician involvement, like much of chemotherapy administration.¹⁶ The modifications were intended to correct perceived low payments for these services, but instead resulted in reduced payments for some of these services, particularly those provided by oncologists. Further, the agency reduced oncology's reported supply expenses, one of the data elements used to compute fees, to keep from paying twice for drugs that are reimbursed separately by Medicare. Oncologists acknowledge that the supply expense estimate needed to be reduced, but argue that the reduction was too large. We recommended in our October 2001 report that

¹⁶In the case of chemotherapy drugs, the common practice is for a nurse employed by a physician to administer the drug and for the physician to bill Medicare.

CMS revert to using the basic methodology to determine practice expense payments for all services and develop the appropriate data to more accurately estimate oncology supply expenses. If these recommendations had been followed in 2001, we estimate that payments to oncologists would have been about \$51 million higher.

Similar to the physicians who bill for outpatient drugs, pharmacy suppliers and their representatives contend that the overpayments for DME-related drugs are needed to compensate them for costs not covered by Medicare—that is, clinical, administrative, and other labor costs associated with delivering the drug. These include costs for billing and collection; facility and employee accreditation; licensing and certifications; and printed patient education materials. Medicare pays a \$5 dispensing fee for inhalation therapy drugs used with a nebulizer, the vast majority of the pharmacy-supplied drugs. The fee is higher than dispensing fees paid by pharmacy benefit managers for private insurance plans, which average around \$2, and comparable to fees paid by state Medicaid programs, which range from \$2 to more than \$6.

Besides payments for the DME-related drugs, pharmacy suppliers may receive additional compensation through the payment for DME and related supplies. Our prior work shows that, for two reasons, Medicare DME and supply payments may exceed market prices.¹⁶ First, because of an imprecise coding system, Medicare carriers cannot determine from the DME claims they process which specific products the program is paying for. Medicare's coding system groups products that may have significantly different characteristics and, therefore, different prices. Medicare, however, pays one fee for all products classified under a single billing code, regardless of whether their market prices are below or above that fee.¹⁷ Second, DME fees are often out of line with current market prices. Until recently, DME fees had generally been adjusted only for inflation since the process required to change the fees for any other reason was lengthy and cumbersome. As a result, payment levels may not reflect changes in technology and other factors that could significantly change market prices.

¹⁶ U.S. General Accounting Office, *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies*, GAO/HEHS-98-102 (Washington, DC: May 12, 1998).

¹⁷ The equipment and supply payment is determined from a DME fee schedule, whose rates are based on a state-specific fee schedule and subject to national minimum and maximum payment limits.

Other Purchasers' Practices Are Instructive for Reforming Medicare Payments for Covered Outpatient Drugs

Private insurers and federal agencies, notably VA, employ varying approaches in paying for drugs, generally using the leverage of their volume and competition to secure better prices. While private payers can negotiate with some suppliers to the exclusion of others and arrive at terms without clear criteria or a transparent process to secure lower prices, some of these practices would not be acceptable for a public program like Medicare, given the program's size and need to ensure access for providers and beneficiaries. VA uses the leverage of federal purchasers to secure verifiable data on actual market transactions by private purchasers to establish FSS prices for federal agency and public hospital purchasers. VA also uses competition to secure even lower prices in purchasing selected drugs for its own facilities. In considering how these approaches might prove instructive for Medicare, the program's unique responsibilities and characteristics need to be carefully considered to avoid untoward consequences for beneficiaries and providers.

VA sets FSS prices based on actual prices paid by private purchasers—specifically, the prices that drug manufacturers charge their “most-favored” private customers.¹⁸ In exchange for state Medicaid programs covering their drugs, manufacturers agree to offer VA and other government purchasers drugs at these prices. To enable VA to determine the most-favored customer price, manufacturers provide information on price discounts and rebates offered to domestic customers and the terms and conditions involved, such as length of contract periods and ordering and delivery practices.¹⁹ Manufacturers must also be willing to supply similar information to CMS to have their drugs covered by Medicaid. The information is the basis for rebates required by the Medicaid program. With Congressional sanction, CMS might utilize this information to determine appropriate prices for Medicare that would be based on actual prices being paid in the market. Medicare prices most likely could not be the prices paid by most favored customers, but would need to be high enough to assure access for all beneficiaries.

¹⁸Under federal procurement regulations, the government seeks to obtain a price that is intended to equal or better the price that the manufacturer offers its most-favored nonfederal customer under comparable terms and conditions.

¹⁹Because the terms and conditions of commercial sales vary, there may be legitimate reasons why the government does not always obtain the most-favored customer price. Hence, under the regulations, VA may accept a higher price if it determines that (1) the price offered to the government is fair and reasonable and (2) awarding the contract is otherwise in the best interest of the government.

VA has been successful in using competitive bidding to obtain even more favorable prices for certain drugs for its own facilities.²⁰ Through these competitive bids, VA has obtained national contracts for selected drugs at prices that are even lower than FSS prices. These contracts seek to concentrate the agency's purchase on one drug within a class of therapeutically equivalent products for the agency's national formulary. In 2000, VA contract prices averaged 33 percent lower than corresponding FSS prices.

Medicare's use of competition has been restricted to several demonstration projects authorized by the Balanced Budget Act of 1997.²¹ In one of these demonstrations under way in San Antonio, Texas, suppliers bid to provide nebulizer drugs, such as albuterol, to Medicare beneficiaries. While Medicare normally allows any qualified provider to participate in the program, only 11 bidders for nebulizer drugs were selected to participate under the demonstration. In exchange for restricting their choice of providers to the 11 suppliers, beneficiaries are not liable for any differences between what suppliers charge and what Medicare allows. Preliminary CMS information on the San Antonio competitive bidding demonstration suggests no reported problems with access and a savings of about 26 percent for the inhalation drugs. Expanding competitive bidding for additional drugs could be beneficial. However, use of competitive bidding would not be feasible for all drugs, for example, those that have no or few therapeutic equivalent alternatives, which is the case for many chemotherapy drugs.

Concluding Observations

Our September 2001 study on Medicare payments for outpatient drugs shows that Medicare payments and Medicare beneficiary copayments to providers for these drugs are much higher than necessary, given what the providers likely paid to purchase these drugs from manufacturers, wholesalers, or other suppliers. Unlike the market-based fees paid by VA and other federal agencies, Medicare's fees are based on AWP, which is a manufacturer-reported amount that generally does not reflect actual transactions between seller and purchaser. Physicians contend that the profits they receive from Medicare's payments for outpatient drugs are needed to compensate for inappropriately low Medicare fees for most

²⁰U.S. General Accounting Office, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes*, GAO/HEHS-00-118 (Washington, DC: August 7, 2000).

²¹Pub. L. No. 105-33, §4319, 111 Stat. 251, 392.

drug administration services. Similarly, the case argued by some pharmacy suppliers for Medicare's high drug payments is that not all of their costs of dispensing the drugs are covered.

If Medicare were to follow the principle of paying for each service appropriately and incorporate lessons from other payers in setting fees for outpatient drugs, the program would use information on actual market prices, accounting for rebates and discounts, to establish its payments for drugs. Manufacturers whose drugs are used by veterans or Medicaid recipients are already required to provide this information to VA and CMS. Medicare could also determine market-based fees for certain drugs through competitive bidding. If drug payments are tied closer to providers' likely acquisition costs, Medicare would need to ensure that separate and appropriate payments are made to pay for the administration and delivery of covered drugs. Changes to Medicare payments for chemotherapy administration under the current physician fee schedule are needed to make these payments comparable to payments for other services. While Medicare also provides a separate payment for the dispensing of inhalation therapy drugs, dispensing fees for other drugs that physicians do not administer need to be considered. Different methods of determining these payments may be necessary because of differences in the way certain drugs are supplied and administered. Paying for these services explicitly would enable Medicare to eliminate implicit payments that may have been made through excessive payments for DME and the drugs associated with the DME payment.

Any change to Medicare's payments, particularly a reduction in fees, for covered outpatient drugs or related administration or delivery services needs to be accompanied by an ongoing assessment of whether the new fees adequately support Medicare beneficiaries' access to the drugs and services. Such monitoring should involve examining recent use of these services so that prompt fee adjustments can be made if access problems are found.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions that you or other Subcommittee Members may have.

Contact and Acknowledgments

For further information regarding this testimony, please contact me at (202) 512-7119. Kathryn Linehan, James Mathews, and Michael Rose made contributions to this statement.

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